

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Kleinschmidt *et al.*

Serial No.: To be assigned

Group Art Unit: 1648

Filed: Herewith

Examiner: Winkler, U.

For: AAV-DNA COMPRISING HELPER
VIRUS SEQUENCES

Attorney Docket No.: 8484-101-999

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:
 - 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
 - 1b. A legible copy of:
 - ☐ Each U.S. patent application publication and U.S. and foreign patent;
 - ☐ Each publication or that portion which caused it to be listed on the PTO-1449;
 - ☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
 - ☐ all other information or portion which caused it to be listed on the PTO-1449.
 - 1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
 - 1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
 - ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);

CA1 - 281475.1

- ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
 - ☐ Before the mailing of the first Office action on the merits;
 - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
 - ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(i)(1) is:

- ☐ enclosed.
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement *(applicable if Item 3a or Item 4 is checked)*

(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
6. ☒ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☒ Copies of publications listed on Form PTO-1449 from prior application Serial No. 09/676,223, filed on September 29, 2000, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check either Item 7a or 7b)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on _____. A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on _____.
- 7b. ☐ This Supplemental Information Disclosure Statement is timely filed within one (1) month of a PTO Notice under 37 C.F.R. §1.97(i).
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- (Check Item 8a, 8b, or 8c)
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date August 3, 2001

Nathan Machin
Nathan A. Machin

47,763
(Reg. No.)

For Laura A. Coruzzi (Reg. No. 30,742)
PENNIE & EDMONDS LLP
1155 Avenue of Americas
New York NY 10036-2720
(212) 790 - 9090

LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i>				ATTY. DOCKET NO.		APPLICATION NO.	
				8484-0087-899		09/676,223	
				APPLICANT			
				Kleinschmidt et al.			
INT'L FILING DATE				GROUP			
September 29, 2000				to be assigned			
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,872,005	02/16/99	Wang et al.			
	AB	6,004,797	12/21/99	Colosi			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	AC	WO 95/06743	03/09/95	PCT			
	AD	WO 96/18727	06/20/96	PCT			
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AE	Chartier et al., 1996, "Efficient Generation of Recombinant Adenovirus Vectors by Homologous Recombination in <i>Escherichia coli</i> ," <u>Journal of Virology</u> 70(7):4805-4810					
	AF	Clark et al., 1995, "Cell Lines for the Production of Recombinant Adeno-Associated Virus," <u>Human Gene Therapy</u> 6(10):1329-1341					
	AG	Colosi et al., 1995, "AAV Vectors Can Be Efficiently Produced Without Helper Virus," <u>Blood</u> 86(10 Suppl. 1):627A					
	AH	Fasel et al., 1982, "The region of mouse mammary tumor virus DNA containing the long terminal repeat includes a long coding sequence and signals for hormonally regulated transcription," <u>EMBO Journal</u> 1(1):3-7					
	AI	Flotte et al., 1995, "An improved system for packaging recombinant adeno-associated virus vectors capable of in vivo transduction," <u>Gene Therapy</u> 2(1):29-37					
	AJ	Laughlin et al., 1983, "Cloning of infectious adeno-associated virus genomes in bacterial plasmids," <u>Gene</u> 23(1):65-73					
	AK	Stratford-Perricaudet et al., 1992, "Widespread Long-term Gene Transfer to Mouse Skeletal Muscles and Heart," <u>J. Clin. Invest</u> 90:626-630					
EXAMINER				DATE CONSIDERED			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Duplicate